REMARKS

Claim 12 has been amended by deleting the phrase "improving the homogeneity of the color of human skin in need of improving the homogeneity of color."

Claims 12, 13, 16-24, 27-33 and 36-45 are currently pending, although claims 36-45 have been withdrawn from consideration.

Initially, Applicants would like to thank the Examiner for the indication that claims 23, 24 and 27-33 contain allowable subject matter.

The Office Action rejected claims 12, 13, 16-19 and 22 under 35 U.S.C. § 102 as anticipated by U.S. patent 4,542,129 ("Orentreich") and/or U.S. patent 5,869,090 ("Rosenbaum"). The Office Action also rejected claims 12, 13, 16-22 under 35 U.S.C. § 103 as obvious over JP 07196467 ("Nobuo") and Orentreich in view of U.S. patent 5,776,438 ("Tokue"). In view of the following comments, Applicants respectfully request reconsideration and withdrawal of these rejections.

In support of the above rejections, the Office Action asserted that everyone would want to improve skin homogeneity, leading to the conclusion that Orentreich and Rosenbaum inherently disclose the claimed methods and that motivation to combine Nobuo, Orentreich and Tokue to practice the claimed methods would have existed based upon this universal desire. This assertion has been rendered moot by the above amendment to claim 12 deleting the phrase "improving the homogeneity of the color of human skin in need of improving the homogeneity of color." Thus, the presently claimed methods, which relate to methods of depigmenting, bleaching and/or pro-pigmenting human skin in need thereof, are not inherently practiced in the prior art, nor does the prior art motivate one skilled in the art to practice the claimed methods.

More specifically, the case of *Jansen v. Rexall Sundown Inc.*, 68 U.S.P.Q.2d 1154 (Fed. Cir. 2003) resolves the prior art issues in this case, and requires that the currently pending rejections be withdrawn.

In *Jansen*, the claims were directed to methods of treating or preventing macrocytic-megaloblastic anemia comprising administering effective amounts of folic acid and vitamin B_{12} to humans in need thereof. *Jansen* at 1157. In interpreting these claims, the Federal Circuit ruled that the claims require the specific intent to achieve the claimed objective (treatment or prevention of macrocytic-megaloblastic anemia). Specifically, the Federal Circuit stated that:

> . . . the claim preamble sets forth the objective of the method, and the body of the claim directs that the method be performed on someone 'in need.' In both cases, the claims' recitation of a patient or a human 'in need' gives life and meaning to preambles. [Citation omitted]. The preamble is therefore not merely a statement of effect that may or may not be desired or appreciated. Rather, **it is a statement of the intentional purpose for which the method must be performed**. We need not decide whether we would reach the same conclusion if either of the 'treating or preventing' phrase or the 'to a human in need thereof' phrase was not a part of the claim; **together, however, they compel the claim construction arrived at by both the district court and this court**.

Jansen at 1158 (emphasis added). The Federal Circuit further explained that:

> the '083 patent claims are properly interpreted to mean that the combination of folic acid and vitamin B_{12} **must** be administered to a human with a recognized need to treat or prevent macrocytic-megaloblastic anemia.

Jansen at 1158 (emphasis added).

Thus, according to the Federal Circuit, claims directed to methods of treatment to be performed on those in need of such treatment require the specific intent to effect such treatment.

In the present application, the pending claims are directed to methods of depigmenting, bleaching and/or pro-pigmenting human skin in need thereof. In accordance with the Federal Circuit's decision in *Jansen*, these claims must be interpreted to require the specific intent to effect depigmentation, bleaching and/or pro-pigmentation of human skin.

Orentreich and Rosenbaum neither teach nor suggest such specific intent: that is, Orentreich and Rosenbaum do not state that the claimed DHEA compounds could or should be used to depigment, bleach and/or pro-pigment human skin. Orentreich and Rosenbaum neither describe nor suggest that any DHEA compound, itself, possesses the necessary activity to depigment, bleach and/or pro-pigment human skin. Thus, nothing in Orentreich or Rosenbaum would lead one skilled in the art to believe that DHEA compounds possess skin depigmentation, bleaching and/or pro-pigmentation activity, or to use the claimed DHEA compounds for this express purpose. Accordingly, Orentreich and Rosenbaum cannot teach or suggest using an effective amount of the claimed DHEA compounds with the intent of achieving the desired depigmentation, bleaching and/or pro-pigmentation result on skin, so Orentreich and Rosenbaum cannot teach or suggest the claimed methods.

As noted above, the Office Action indicated a belief that the cited art inherently results in the claimed methods, thereby rendering such methods unpatentable. Such an inherency argument is inapplicable in this case.

In *Jansen*, the Federal Circuit discussed its earlier decision in *Rapoport v. Dement*, 254 F.3d 1053 (Fed. Cir. 2001) (copy enclosed). In *Rapoport*, the claims were directed to methods of treating sleep apneas comprising administering an effective amount of an

azapirone compound to a patient in need of such treatment. In *Jansen*, the Federal Circuit characterized its *Rapoport* decision as follows:

> We rejected [the argument that prior art disclosing treatment of a symptom of sleep apnea actually disclosed treatment of sleep apnea in *Rapoport*], stating, 'There is no disclosure in the [prior art reference that the compound] is administered to patients suffering from sleep apnea *with the intent to cure the underlying condition.*' Thus, the claim was interpreted to require that the method be practiced with the intent to achieve the objective stated in the preamble.

Jansen at 1157 (emphasis in original).

In *Rapoport*, the Federal Circuit addressed the issue of inherency (that is, whether prior art related to treating symptoms of sleep apnea inherently anticipated the claimed methods of treating sleep apnea). The Federal Circuit rejected this argument on two independent grounds.

First, and most importantly, the Federal Circuit noted that prior art did not disclose administering the compound to patients suffering from sleep apnea. *Rapoport* at 1062. Thus, as noted in *Jansen*, the prior art did not disclose administering the compound to patients suffering from sleep apnea "*with the intent to cure the underlying condition.*" Similarly, prior art which does not disclose applying a depigmenting, bleaching and/or pro-pigmenting effective amount of a DHEA compound to skin in need of such depigmentation, bleaching and/or pro-pigmentation cannot inherently anticipate or render obvious the claimed methods. For this reason alone the prior art rejections are improper and should be withdrawn.

The second independent ground was that it had not been demonstrated that the prior art regimen would necessarily result in treating sleep apnea even assuming such a regimen were administered to one suffering from sleep apnea. *Rapoport* at 1062-63. Similarly, reproducing the cited prior art in this case would not necessarily result in practicing the

claimed methods. For this reason as well the prior art does not inherently anticipate or render obvious the claimed invention.

In view of the above, Applicants respectfully request that the rejections under § 102 be reconsidered and withdrawn.

Regarding the rejection under § 103, neither Nobuo nor Tokue compensates for Orentreich's fatal deficiencies. That is, neither Nobuo nor Tokue teaches or suggests applying a DHEA compound to skin with the specific intent to depigment, bleach and/or pro-pigment the skin as required by the claims.

In view of the above, Applicants respectfully request that the rejections under § 103 be reconsidered and withdrawn.

Applicants believe that the present application is in condition for allowance. Prompt and favorable consideration is earnestly solicited.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
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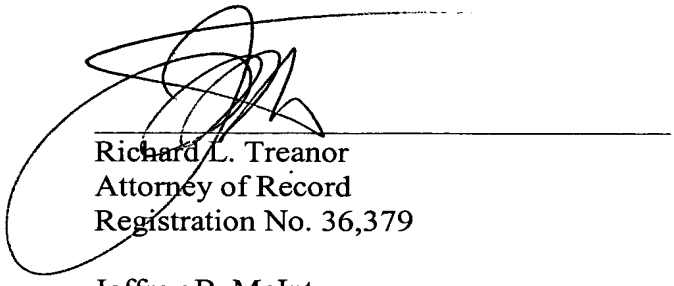

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license is exclusive, it may be tantamount to an assignment of the patent. In neither case is the invention of the patent necessarily on sale when the license is executed. In fact, if a license were equivalent to a sale for purposes of the on-sale bar, many patents would be invalidated long before the invention itself is put on sale because the grant of licenses often long precedes commercialization by sale of the invention. The law does not start the on-sale bar clock running when a license to an invention is executed.

The on-sale bar is intended to limit the time for an inventor to commercialize an invention before filing a patent application. The statute refers to a patented invention itself being on sale, not to an agreement with another party concerning the commercialization of the invention at some future time, following which the invention would then be placed on sale. An important consequence of the distinction between the sale and the license of a patented machine is thus the time at which the on-sale clock starts running. With a license, the licensee of a machine would not normally be able to immediately begin commercialization of the invention, whereas if the machine had been sold, the sale itself is the commercialization that starts the on-sale clock running. How long Hallmark, the potential licensee in this case, would have taken before it could have put the invention into commercial use is not known. But it would not have been immediate, whereas the sale of the machine, had it occurred, would have been immediate.

There may be instances in which a license is tantamount to a sale, and in which a bar may arise from a license. When a product, such as a computer program, is transferred to a customer in a transaction that is tantamount to a sale, the transaction may under commercial law nevertheless still be a license. The transaction is structured as a license (a "shrink wrap" license) so that the seller can restrict what the "buyer" does with the program, in particular, to ensure that it is not duplicated and distributed to others who have not paid the seller for the product. The product is, however, just as immediately transferred to the "buyer" as if it were sold. Notwithstanding the provisions of such a license, it is not contemplated that the product will ever be returned to the seller.

This is not such a case. The license offered here, in contrast to an offer for sale of the patented machine, contemplated that Hallmark go into the business of using the patented machine and method to curl ribbon, which Hallmark would then sell. The on-sale bar was not triggered by the offered license. Thus, I would hold that no on-sale bar occurred for the additional reason that the proposal for a business arrangement between Goldstein and Hallmark was an offer to grant a license under the eventual patent, not an offer to sell the patented machine.

David M. RAPOPORT, Appellant,

v.

William C. DEMENT, Mark R. Rosekind, and Jeffrey L. Schwimmer, Appellees.

No. 00–1451.

United States Court of Appeals, Federal Circuit.

June 28, 2001.

Patent interference proceeding was brought before the Patent and Trademark

Office (PTO) Board of Patent Appeals and Interferences concerning claims for drug to treat sleep apnea. Board assigned interference No. 102,760 to the claims and assigned priority to senior applicant. Junior applicant appealed. The Court of Appeals, Clevenger, Circuit Judge, held that senior applicant's claim was not anticipated or rendered obvious by prior art reference to use of drug to treat anxiety in patients suffering from sleep apnea disorder.

Affirmed.

1. **Patents ⇐51(1), 72(1)**

To anticipate patent claim, prior art reference must disclose every limitation of claimed invention, either expressly or inherently. 35 U.S.C.A. § 102(a).

2. **Patents ⇐114.25**

Whether patent claim limitation is inherent in prior art reference, for purpose of anticipation analysis, is factual issue on which evidence may be introduced. 35 U.S.C.A. § 102(a).

3. **Patents ⇐114.25**

Patent Interference Board's determination of obviousness is question of law subject to de novo review, but its factual determinations underlying its ruling obviousness are reviewed under substantial evidence test. 35 U.S.C.A. § 103.

4. **Patents ⇐114.25**

Patent Interference Board's decisions to deny motion to accept belated filing and to dismiss belated motion for judgment are reviewed for abuse of discretion.

5. **Patents ⇐114.25**

Abuse of discretion occurs if Patent Infringement Board's decision: (1) is clearly unreasonable, arbitrary, or fanciful; (2) is based on erroneous conclusion of law; (3) rests on clearly erroneous fact finding; or (4) involves record that contains no evidence on which Board could rationally base its decision.

6. **Patents ⇐106(1)**

"Method for treatment of sleep apneas," called for in patent interference count, was limited to treatment of underlying sleep apnea disorder itself, and did not include treatment of secondary symptoms.

7. **Patents ⇐106(1)**

Senior applicant's patent claim for treatment of sleep apneas with particular drug was not anticipated or rendered obvious by junior applicant's prior art reference to use of drug to treat anxiety in patients suffering from sleep apnea disorders, for purpose of determining priority in interference proceeding. 35 U.S.C.A. §§ 102(g), 103.

8. **Patents ⇐114.25**

Determination of what prior art reference teaches is question of fact, which will be affirmed on appeal if supported by substantial evidence.

9. **Patents ⇐106(1)**

Patent Interference Board did not abuse its discretion, in interference proceeding, by denying motion to accept belated filing and dismissing belated motion for judgment, absent showing of sufficient cause why motions were not filed sooner. 37 C.F.R. § 1.645(b).

Roger L. Browdy, Browdy and Neimark, P.L.L.C, of Washington, DC, argued for appellant.

David S. Abrams, Roylance, Abrams, Berdo & Goodman, L.L.P., of Washington, DC, argued for appellee. With him on the brief was Robert H. Berdo.

Before CLEVENGER, RADER and GAJARSA, Circuit Judges.

CLEVENGER, Circuit Judge.

David M. Rapoport ("Rapoport") appeals from a final decision of the Board of Patent Appeals and Interferences of the United States Patent and Trademark Office ("Board") dated February 29, 2000. The real parties in interest in this interference are: (1) New York University ("NYU"), assignee of Rapoport; (2) the Board of Trustees of the Leland Stanford Junior University ("Stanford"), assignee of William C. Dement ("Dement") and Mark R. Rosekind ("Rosekind"); and (3) the Bristol Myers Squibb Company ("Bristol Myers"), assignee of Jeffrey L. Schwimmer ("Schwimmer"). Collectively, Dement, Rosekind, and Schwimmer will be referred to herein as "Dement et al."

The Board awarded judgment of priority as to the sole count of the interference in favor of Dement et al., and further ordered that Dement et al. are entitled to a patent containing claims 1–13 of U.S. Patent Application No. 07/695,325 ("the '325 application"), filed May 3, 1991, and that Rapoport is not entitled to a patent containing claims 1–12 of U.S. Patent Application No. 07/479,693 ("the '693 application"), filed February 14, 1990. We affirm.

I

The subject matter at issue in this case is a method for the treatment of sleep apnea. Generally, sleep apnea refers to the transient cessation of breathing during sleep. As described by the Board:

> Sleep apneas comprise a spectrum of disorders with varying severity and morbidity and are usually classified as being an obstructive, central, or mixed apnea, depending on the presence or absence of respiratory efforts during the periods in which airflow has ceased. Obstructive and mixed apneas occur with greatest frequency with the most familiar being obstructive sleep apnea syndrome in which sporadic recurring collapse of the patient's upper airway occurs during sleep. If the collapse is complete, there is no air exchange at the nose and mouth and breathing is interrupted. The usual result is a partial arousal and a return to normal breathing.

In most instances, patients suffering from sleep apnea have no knowledge or memory of the apnea episodes, but find themselves constantly suffering from fatigue and daytime drowsiness for no apparent reason. Consequently, due to this chronic lack of proper rest, patients who suffer from sleep apnea often exhibit secondary symptoms of anxiety, depression, fatigue, malaise, irritability, anger, hostility, and other similar problems.

The count in this interference relates to the treatment of sleep apnea by administering a therapeutically effective amount of certain azapirone compounds such as buspirone "to a patient in need of such treatment."

On February 12, 1990, Schwimmer filed U.S. Patent Application No. 07/478,820 ("the '820 application"). Claim 1 of the '820 application as originally filed reads in relevant part:

> 1. A method for treatment of sleep apneas comprising administration of a therapeutically effective regimen of a Formula I azapirone compound or a pharmaceutically effective acid addition salt thereof to a patient in need of such treatment....

There is no dispute that although buspirone is an azapirone compound, the azapirone compounds of Schwimmer's Formula I exclude buspirone. On the same day, Dement, Rosekind, and Schwimmer jointly filed U.S. Patent Application No. 07/479,-

803 ("the '803 application"). Original claim 1 of the '803 application reads as follows in its entirety:

> 1. A method for treatment of sleep apneas comprising administration of a therapeutically effective regimen of buspirone or a pharmaceutically effective acid addition salt thereof to a patient in need of such treatment.

Two days later, on February 14, 1990, Rapoport filed the '693 application. Claim 1 of the '693 application reads as follows in relevant part:

> 1. A method for treatment of sleep apneas comprising administration of a therapeutically effective regimen of a Formula I azapirone compound or a pharmaceutically effective acid addition salt thereof to a patient in need of such treatment....

The azapirone compounds of Rapoport's Formula I include buspirone, and claim 6 of Rapoport's '693 application is specifically directed to buspirone.

On February 12, 1991, Schwimmer filed U.S. Patent Application No. 07/657,332 ("the '332 application") as a continuation of the '820 application, and on May 3, 1991, Dement, Rosekind, and Schwimmer jointly filed the '325 application as a continuation-in-part of the '803 and '332 applications. Original claim 1 of the '325 application reads as follows in relevant part:

> 1. A method for treatment of sleep apneas comprising administration of a therapeutically effective amount of a Formula I azapirone compound or a pharmaceutically effective acid addition salt thereof to a patient in need of such treatment....

The azapirone compounds of Formula I in the context of the '325 application include buspirone, and claim 7 of the '325 application is specifically directed to buspirone.

On January 10, 1992, an interference was declared, and Dement et al. were accorded the benefit of the February 12, 1990, filing date of the '820 and '803 parent applications and therefore designated as the senior party. Count 1 of the interference, the only count at issue, reads in pertinent part as follows:

> A method for treatment of sleep apneas comprising administration of a therapeutically effective amount of a Formula I azapirone compound or a pharmaceutically effective acid addition salt thereof to a patient in need of such treatment....

The azapirone compounds of Formula I in the context of the interference count include buspirone. Claims 1–12 of Rapoport's '693 application and claims 1–13 of the Dement et al. '325 application correspond to the count.

On June 10, 1992, Rapoport filed a Motion for Judgment pursuant to 37 C.F.R. § 1.633(a) in which he argued, *inter alia*, that the subject matter of the count was not patentable to Dement et al., on the grounds that it was anticipated and/or rendered obvious pursuant to 35 U.S.C. § 102(a) and/or 35 U.S.C. § 103 by a prior art reference authored by Rapoport. This reference, entitled "Buspirone: Anxiolytic Therapy with Respiratory Implications," was published in *Family Practice Recertification* in September 1989, at pages 32–37 of Vol. 11, No. 9 (Supplement) ("the FPR Publication"). We note that the FPR Publication does not constitute a statutory bar against either Dement et al. or Rapoport, since it was published less than one year before the priority filing date of the '325 and '693 applications. 35 U.S.C. §§ 102(a) and 102(b) (1994). However, because the FPR Publication was authored by Rapoport, it can be cited as prior art against Dement et al., but not against Rapoport. 35 U.S.C. § 102 (1994); *In re Katz*, 687

F.2d 450, 454, 215 USPQ 14, 17 (CCPA 1982). Dement *et al.* do not contest the fact that the FPR Publication is a prior art reference that may be cited against them in this interference.

On October 29, 1992, pursuant to 37 C.F.R. § 1.602(b), Dement and Rosekind disclosed that they were obligated to assign their rights in the '325 application to Stanford, and Schwimmer disclosed that he was obligated to assign his rights to Bristol Myers. Approximately eight months later, on June 21, 1993, Dement et al. explicitly stated on the record that Schwimmer was the sole inventor of the use of most of the azapirone compounds covered by the count except for buspirone in the treatment of sleep apnea. On July 9, 1993, Rapoport filed a Second Motion to Accept Belated Filing Of Preliminary Motion Under 37 C.F.R. § 1.633(a) ("Rapoport's Motion to Accept Belated Filing"), along with a Motion for Judgment Under C.F.R. § 1.633(a) ("Rapoport's Belated Motion for Judgment") arguing that claims in the Dement et al. '325 application are unpatentable under 35 U.S.C. § 102(g) and/or § 103 over the prior invention of claims 7 and 13 of Dr. Dement, which were invented by a different inventive entity.

On April 12, 1996, the Board rendered a decision which, *inter alia*, denied Rapoport's June 10, 1992, Motion for Judgment, denied Rapoport's Motion To Accept Belated Filing, and dismissed Rapoport's Belated Motion for Judgment as being untimely. These decisions were adhered to in a decision for reconsideration dated September 6, 1996. The Board rendered its final decision on February 29, 2000.

In its decision dated April 12, 1996, the Board found that: (1) Rapoport had established a conception date of May 13, 1988; (2) Dement was entitled to a 1986 date of conception; and (3) the conception by Dement inures to the benefit of Dement et al. pursuant to 35 U.S.C. § 116. Based on these findings, the Board awarded priority of the invention of the interference count to Dement et al. Before this court, Rapoport does not contest either the ultimate priority determination in favor of Dement et al. or the underlying findings by the Board.

Instead, on appeal, Rapoport argues that the Board erred in not finding that all of the Dement et al. claims corresponding to the count are either anticipated by the FPR Publication or rendered obvious by the FPR Publication in combination with admissions allegedly made in the Dement et al. '325 application. Rapoport also argues that it was an abuse of discretion for the Board to deny Rapoport's Motion to Accept Belated Filing and to dismiss Rapoport's Belated Motion for Judgment as being untimely. Finally, Rapoport argues that-in the event that this court finds that all of the Dement et al. claims are unpatentable in view of the FPR Publication—the Board erred in awarding judgment on priority in favor of Dement et al. We have jurisdiction to hear this appeal pursuant to 28 U.S.C. § 1295(a)(4)(A) (1994) and 35 U.S.C. § 141 (1994).

II

[1–3] To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either expressly or inherently. *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir.1997). Anticipation is a question of fact, and we uphold decisions of the Board on factual matters if there is substantial evidence in the record to support the Board's findings. *In re Hyatt*, 211 F.3d 1367, 1371–72, 54 USPQ2d 1664, 1667 (Fed.Cir.2000). Whether a claim limitation is inherent in a prior art reference is a factual issue on which evidence may be introduced. *In re Schreiber*, 128 F.3d at

1477, 44 USPQ2d at 1431. The Board's determination of obviousness is a question of law subject to *de novo* review. However, the Board's factual determinations underlying its rulings on anticipation and obviousness are reviewed under the substantial evidence test. *Dickinson v. Zurko*, 527 U.S. 150, 119 S.Ct. 1816, 144 L.Ed.2d 143, 50 USPQ2d 1930 (1999); *In re Gartside*, 203 F.3d 1305, 1316, 53 USPQ2d 1769, 1775–76 (Fed.Cir.2000). Substantial evidence is "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *In re Gartside*, 203 F.3d at 1312, 53 USPQ2d at 1773 (quoting *Consol. Edison Co. v. NLRB*, 305 U.S. 197, 229, 59 S.Ct. 206, 83 L.Ed. 126 (1938)).

[4, 5] The Board's decisions to deny Rapoport's Motion to Accept Belated Filing and to dismiss Rapoport's Belated Motion for Judgment are reviewed for abuse of discretion. *Abrutyn v. Giovanniello*, 15 F.3d 1048, 1050–51, 29 USPQ2d 1615, 1617 (Fed.Cir.1994). An abuse of discretion occurs if the decision (1) is clearly unreasonable, arbitrary, or fanciful; (2) is based on an erroneous conclusion of law; (3) rests on clearly erroneous fact finding; or (4) involves a record that contains no evidence on which the Board could rationally base its decision. *Id.*

As noted above, Rapoport has not requested review of the underlying factual determinations or of the legal bases for the Board's award of priority to Dement et al. Instead, Rapoport merely questions the Board's action of awarding priority to Dement et al. at the same time as holding the Dement et al. claims patentable. This issue involves the Board's legal conclusions regarding priority, conception, and reduction to practice, which we review *de novo*. *Eaton v. Evans*, 204 F.3d 1094, 1097, 53 USPQ2d 1696, 1698 (Fed.Cir.2000).

III

We first address Rapoport's argument that the Dement *et al.* claims corresponding to the count are anticipated by the FPR Publication. Because the first step of a patentability or invalidity analysis based on anticipation and/or obviousness in view of prior art references is no different from that of an infringement analysis, we must start by interpreting any disputed terms in the interference count. *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1351, 57 USPQ2d 1747, 1751–52 (Fed.Cir.2001). Only when a claim is properly understood can a determination be made whether the claim "reads on" an accused device or method, or whether the prior art anticipates and/or renders obvious the claimed invention. *Id.*

A

[6] Rapoport argues on appeal, as he did before the Board, that it is reasonable to interpret the phrase "method for treatment of sleep apneas" in the interference count broadly to include both (1) treatment of anxiety secondary to sleep apnea and (2) treatment of the underlying sleep disorder itself. In contrast, Dement et al. agree with the Board, which found that in the context of the present interference, treatment of the underlying sleep apnea disorder itself is distinct from treatment of anxiety and other secondary symptoms related to sleep apnea. Based on this finding, the Board interpreted the term "treatment of sleep apneas" in the interference count as being limited to treatment of the underlying sleep apnea disorder itself. We review the Board's legal conclusion, as we do all rulings on claim interpretation, without deference. *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1456, 46 USPQ2d 1169, 1174–75 (Fed.Cir.1998) (en banc); *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979, 34 USPQ2d

1321, 1329 (Fed.Cir.1995) (en banc), *aff'd*, 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577, 38 USPQ2d 1461 (1996). Upon reviewing the record, we discern no error with the Board's interpretation.

First, we note that the disputed phrase "treatment of sleep apneas" is technically part of the preamble of the interference count, because it appears before the transition word "comprising." However, there is no dispute in this case that the phrase should be treated as a claim limitation. Moreover, without treating the phrase "treatment of sleep apneas" as a claim limitation, the phrase "to a patient in need of such treatment" would not have a proper antecedent basis.

In support of his proposed broad interpretation for "treatment of sleep apneas," Rapoport relies on the following passage from the written description of the Dement et al. '325 application:

> There are two aspects to the use of azapirones in treating sleep apneas. The first is that the administration of an azapirone effectively reduces the frequency and severity of the apnea episodes during sleep. This is reflected in significantly increased undisturbed sleep and a significant increase in blood oxygen levels. The second aspect involves azapirone alleviation of the symptomatology associated with the occurrence of sleep apneas. The azapirone treatment alleviates the sleep apnea-related symptoms of anxiety, depression, fatigue, malaise, irritability, anger and hostility.

According to Rapoport, this passage supports the notion that "treatment of sleep apneas" in the interference count should include both treatment of the underlying disorder and the "symptomatology associated with the occurrence of sleep apneas." However, to the extent that the above passage suggests that "alleviation of the symptomatology associated with the occurrence of sleep apneas" constitutes an aspect of the use of azapirones in treating sleep apneas, the intrinsic record in this case leads to the conclusion that "treatment of sleep apneas" refers only to treatment of the underlying sleep apnea disorder.

First, the plain language of the interference count unambiguously refers to "treatment of sleep apneas" narrowly defined, and does not also include by its plain terms "treatment of symptoms associated with sleep apneas." *See Davis v. Loesch*, 998 F.2d 963, 968, 27 USPQ2d 1440, 1444 (Fed.Cir.1993) ("Interference counts are given the broadest reasonable interpretation possible, and resort to the specification is necessary only when there are ambiguities inherent in the claim language or obvious from arguments of counsel.") (citations omitted); *In re Hyatt*, 211 F.3d at 1372, 54 USPQ2d at 1667 (during examination proceedings, claims are given their broadest reasonable interpretation consistent with the specification). Here, Rapoport relies on the written description of the Dement et al. '325 application in an unsuccessful attempt to broaden the phrase "treatment of sleep apneas" from its ordinary meaning, which narrowly refers to treatment of the underlying disorder itself.

Contrary to Rapoport's assertions, the written description of the Dement et al. '325 application actually confirms the Board's interpretation, and explicitly defines "sleep apneas":

> In the context of this invention, sleep apneas comprise all the sub-categories such as those caused by upper airway obstruction; those whose origins arise in the central nervous system; and those of a mixed type with contribution from both components.

This passage indicates that the term "treatment of sleep apneas" refers to re-

ducing or eliminating sleep apneas caused by upper airway obstructions, sleep apneas whose origins arise in the central nervous system, and sleep apneas of a mixed type.

As further support for the Board's position, the Summary of the Invention in the Dement et al. '325 application states that "[f]or use in the instant method oral administration of a dose of from about 10 to 60 mg of an azapirone at the hour of sleep is usually employed." This description is consistent with treatment of the underlying sleep apnea disorder, which by definition manifests itself during sleep, and inconsistent with treatment of anxiety and other symptoms commonly associated with sleep apnea, which would obviously manifest themselves while a patient is awake.

Next, in a portion of the Detailed Description of the Invention not limited to any particular embodiment, the Dement et al. '325 application states as follows:

> [T]he present invention concerns a method for treating sleep apneas comprising obstructive, central and mixed apneas, in a patient population that ranges from infants to geriatric-aged individuals.

Once again, this passage defines sleep apneas in terms of the underlying respiratory disorder and uses the term "treating sleep apneas" in a manner that is consistent with the Board's interpretation.

Finally, when describing the effectiveness of the sleep apnea treatment method that is disclosed and claimed in the Dement et al. '325 application, the discussion is limited to the treatment's effect on the underlying sleep apnea disorder, and does not mention the treatment's effect on the associated symptomatology:

> The effectiveness of azapirone treatment of patients suffering from sleep apneas can be exemplified by clinical experience with buspirone. Single dose administration of buspirone, given at bedtime to patients suffering from obstructive sleep apnea, resulted in increased sleep efficiency with experimentally derived measurements showing a gain in total sleep time and a marked reduction in episodes of sleep disturbance. One of the most consistent physiological measurements of improvement was a 10 to 20% increase in blood oxygen levels, an indication of improved respiratory efficiency.

In other words, Dement et al. noted that treating patients suffering from obstructive sleep apnea with buspirone at bedtime had a measurably beneficial effect on the underlying sleep apnea disorder (*i.e.*, increased sleep efficiency, gain in total sleep time, significant reduction in episodes of sleep disturbance, and improved respiratory efficiency). However, Dement et al. made no mention in the written description of the '325 application of specific evidence of the treatment's effect on the symptomatology commonly associated with sleep apnea.

We therefore conclude that the Board was correct in interpreting "treatment of sleep apneas" as being limited to treatment of the underlying sleep apnea disorder, *i.e.*, reducing the frequency and severity of the apnea episodes during sleep.

B

[7, 8] Having construed the disputed term in the interference count and affirmed the Board's interpretation, we can properly address the merits of Rapoport's anticipation argument. The Board found that the disclosure of the FPR Publication was limited to treatment of anxiety in patients suffering from sleep apnea with buspirone, and did not address treatment of the underlying sleep apnea disorder. What a reference teaches is a question of fact. *In re Beattie*, 974 F.2d 1309, 1311, 24 USPQ2d 1040, 1041–42 (Fed.Cir.1992).

Therefore, we review the Board's characterization of the disclosure in the FPR Publication for substantial evidence. *In re Gartside*, 203 F.3d at 1316, 53 USPQ2d at 1775–76. The record indicates that substantial evidence supports the Board's factual findings regarding the FPR Publication.

There is no disclosure in the FPR Publication of tests in which buspirone is administered to patients suffering from sleep apnea with the intent to cure the underlying condition. As the Board correctly found, the FPR Publication focuses on the treatment of anxiety with buspirone, and indicates that buspirone has potential as a primary treatment for dyspnea (which simply refers to difficulty in breathing in general).

For example, a passage in the FPR Publication mentions the possibility of administering buspirone to patents suffering from sleep apnea, but this is for the purpose of treating anxiety in such patients, not for the purpose of treating the sleep apnea disorder itself:

> Buspirone thus appears to be an anxiolytic agent with a profile of respiratory effects that make it potentially safer to use for patients with impaired respiratory function and for patients with diseases such as obstructive sleep apnea, when use of ventilatory depressants would be clearly dangerous.

Rapoport concedes as much:

> While this passage does not disclose administering buspirone with the intent of treating the sleep apnea *per se*, such an explicit intent is not necessary in order to anticipate the claims of Dement corresponding to the count.

Rapoport Opening Brief before the Board filed July 5, 1994. In a nutshell, using Rapoport's own words from its Opening Brief before the Board, Rapoport's theory on anticipation is as follows:

> As long as one administers buspirone to a patient with sleep apnea in a therapeutically effective amount, at least claims 1, 2, 6 and 7 of the Dement et al [sic] application underlying the present proceeding are fully anticipated.

In other words, according to Rapoport, neither the reasons for administering buspirone to the patient nor the time of administration are relevant. Instead, according to Rapoport, the only requirement of the count is that the patient suffer from sleep apnea. Given our disagreement with Rapoport's proposed claim interpretation, this argument cannot succeed.

Moreover, the need for tests to confirm safety for treating anxiety in patients with sleep apnea is indicated in the very next sentence of the FPR Publication relating to treating patients suffering from anxiety: "The preliminary results found among healthy subjects need to be confirmed by directly testing patients who need anxiolytic therapy." Thus, even the *proposed* testing in the FPR Publication is limited to the treatment of patients suffering from anxiety, not from sleep apnea. Moreover, the lack of information concerning administration of buspirone to patients while sleeping is indicated in Table 3 of the FPR Publication, where the entry under "Buspirone" regarding its effect on upper airway tone during sleep is "Undetermined."

The Board also correctly found that the FPR Publication does not show administering buspirone in any specific amounts to patients suffering from sleep apnea. Rather, the FPR Publication discloses administering single oral doses of 10 mg to nine normal volunteers. It also discloses administering buspirone in an amount of 10 mg three times a day to two patients with "severe alveolar hypoventilation" who needed anxiolytic therapy to facilitate use of a nocturnal ventilator. There is no

dispute that none of these patients are reported as suffering from sleep apnea in the FPR Publication.

In contrast, as mentioned earlier, the Dement et al. '325 application discloses that based on clinical experience, administration of a single dose of buspirone at bedtime to patients suffering from obstructive sleep apnea resulted in a marked reduction in episodes of sleep disturbance, and further discloses administration of 20–40 mg of buspirone at the hour of sleep to an average adult.

We note that there is no mention in the FRP Publication of administering buspirone to a patient at bedtime. The significance of this fact, of course, is that sleep apnea, by definition, occurs during sleep. In one of the two tests mentioned in the FPR Publication, a single 10 mg dosage was given at an unspecified time, while in the second test buspirone was administered in doses of 10 mg three times a day, once again without specifying administering the buspirone at bedtime.

Finally, we note that Rapoport argues that the FPR Publication inherently anticipates the count even under the Board's claim interpretation. *See In re Graves*, 69 F.3d 1147, 1152, 36 USPQ2d 1697, 1701 (Fed.Cir.1995) (noting that a reference anticipates a claim if it discloses the claimed invention such that a skilled artisan could take the teachings of the reference in combination with his own knowledge of the particular art and be in possession of the invention) (citations omitted). According to Rapoport:

> The anxiolytic amount of buspirone taught by the *FPR* publication still inherently anticipates in view of the fact that the Dement et al. application contains disclosures that anxiolytic amounts of buspirone overlap the preferred therapeutically effective amounts of buspirone disclosed in the Dement et al. application for reducing the frequency and severity of the apnea episodes during sleep.

Specifically, Rapoport bases his argument on the observation that the Dement et al. application specifies administration of buspirone at the hour of sleep in dosages of about 20–40 mg for an average adult. Next, Rapoport notes that the FPR Publication discloses a dosage of 10 mg of buspirone three times a day for treatment of anxiety. The conclusion to be drawn from these observations, according to Rapoport, is as follows:

> The fact that the Dement et al. specification recites a preferred range of 20–40 mg of buspirone administered at the time of sleep does not suggest that the administration of 10 mg of buspirone at the time of sleep, particularly when there have been two other dosages of 10 mg each during the course of the day, will have no therapeutic effect. The claims do not require optimal amounts, only therapeutically effective amounts. If 10 mg of buspirone has any effect on the treatment of sleep apnea, even if not optimum, the claim is anticipated.

We conclude that Rapoport's inherency argument is without merit. First, Rapoport neglects to point out that the FPR Publication explicitly states that the patients who received the 10 mg doses of buspirone three times a day were suffering from "severe alveolar hypoventilation who needed anxiolytic therapy to facilitate the use of a nocturnal ventilator," not from sleep apnea. Second, Rapoport's argument is based on at least two speculative assumptions: (1) that a treatment regimen of three doses a day would necessarily include an administration "at the time of sleep;" and (2) that administering two 10 mg doses of buspirone at unspecified times throughout the day in conjunction with a 10 mg dose of buspirone at bedtime would

necessarily result in a "therapeutically effective amount" of buspirone treatment for the purpose of treating the underlying sleep apnea disorder. "Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient." *Cont'l Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1269, 20 USPQ2d 1746, 1749 (Fed.Cir.1991) (emphasis in original) (citations omitted). Rapoport has not attempted to demonstrate that the proposed dosage regimen in the FPR Publication would necessarily result in a therapeutically effective amount. Instead, Rapoport merely argues that the "preferred" range of 20–40 mg described in the Dement et al. application does not rule out the thrice-daily 10 mg doses of buspirone discussed in the FPR Publication in the context of patients who are not even described as suffering from sleep apnea. The burden of proof, of course, is on Rapoport, by a preponderance of the evidence. *Bruning v. Hirose*, 161 F.3d 681, 685–86, 48 USPQ2d 1934, 1937–38 (Fed.Cir.1998) (copending applications invoke the preponderance of the evidence standard).

Most importantly, however, as we noted at the outset, the issue of anticipation—whether by inherency or otherwise—is a question of fact, and we uphold decisions of the Board on factual matters if there is substantial evidence in the record to support the Board's findings. *In re Hyatt*, 211 F.3d at 1371–72, 54 USPQ2d at 1667. In this case, as detailed above, our review of the record indicates that the Board's findings are amply supported by the evidence. The Board considered the evidence of record and correctly ruled against Rapoport on this issue.

Therefore, for all the reasons stated above, we find that the Board's conclusion that the FPR Publication does not disclose administration of buspirone to patients suffering from sleep apnea to treat sleep apnea is supported by substantial evidence.

IV

[9] Next, we address Rapoport's argument that the Board's action of denying Rapoport's Motion to Accept Belated Filing was an abuse of discretion. As noted earlier, this motion alleged that the Dement et al. claims are either anticipated under 35 U.S.C. § 102(g) and/or rendered obvious under 35 U.S.C. § 102(g) and/or § 103 over the prior invention of claims 7 and 13 of Dr. Dement, which were invented by a different inventive entity.

Our review of the record indicates that the Board denied the Motion to Accept Belated Filing on the basis that Rapoport had filed it on July 9, 1993, approximately eight months after Rapoport should have been aware of the facts upon which the motion was based. As the Board correctly noted, Rapoport should have been aware when the interference was declared that the notice of interference accorded Dement et al. the benefit of the abandoned '820 application, wherein Dr. Schwimmer signed an oath stating that he is the sole inventor of the claimed subject matter (*i.e.*, using azapirones other than buspirone to treat sleep apnea). Moreover, the Board correctly indicated that Rapoport learned or should have been aware of the grounds of unpatentability urged in the preliminary motion for judgment on or about October 29, 1992, when Dement et al. filed a notification pursuant to 37 C.F.R. § 1.602(b) stating that Drs. Dement and Rosekind were obligated to assign their entire interest to Stanford and that Dr. Schwimmer was obligated to assign his entire interest to Bristol Myers.

In view of the above, we conclude that the Board did not abuse its discretion by denying Rappoport's Motion to Accept Be-

lated Filing or in dismissing the preliminary motion for judgment, because there is evidence of record upon which the Board could base its decision that Rapoport did not show "sufficient cause" why the motion was not filed sooner, as required by 37 C.F.R. § 1.645(b).

V

Finally, we turn to Rapoport's argument that the Board erred in awarding judgment on priority in favor of Dement et al. against Rapoport, notwithstanding the possibility that all of the Dement et al. claims could be ruled unpatentable to Dement et al. As Rapoport acknowledges, we need not reach this issue, given our conclusion that the Board did not err in finding that the Dement et al. claims were not rendered unpatentable by the FPR Publication.

VI

For the reasons set forth above, the decision of the Board is, in all respects,

AFFIRMED.

Curt M. READ, Plaintiff–Appellant,

v.

UNITED STATES, Defendant–Appellee.

No. 00–5070.

United States Court of Appeals, Federal Circuit.

June 28, 2001.

Former employee of Federal Aviation Administration brought action to recover back pay under the Back Pay Act after he was removed from his position following revocation of his security clearance. The United States Court of Federal Claims, Diane G. Weinstein, J., dismissed for lack of subject matter jurisdiction, and employee appealed. The Court of Appeals, Friedman, Senior Circuit Judge, held that the Court of Federal Claims lacked jurisdiction under the Civil Service Reform Act.

Affirmed.

1. Federal Courts ⇐1079

Officers and Public Employees ⇐72.22

Only the Merit Systems Protection Board, and not the Court of Federal Claims, is authorized to review removals of federal employees, under the Civil Service Reform Act. 5 U.S.C.A. § 1101 et seq.

2. Officers and Public Employees ⇐72.22

Civil Service Reform Act's (CRSA) comprehensive system for reviewing personnel action taken against federal employees, including administrative review by the Merit Systems Protection Board, displays a clear congressional intent to make Board review the exclusive statutory procedure by which employees may challenge their removal. 5 U.S.C.A. § 1101 et seq.

3. Federal Courts ⇐1079

Officers and Public Employees ⇐72.22

Court of Federal Claims lacked jurisdiction over employee's claim for back pay under Back Pay Act based upon his removal from his position at the Federal Aviation Administration resulting from revocation of his security clearance; under the Civil Service Reform Act, the Merit Systems Protection Board, not the Court of Federal Claims, had jurisdiction to re-